

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: Meagher, Edward

Examiner: Gloria R. Weeks

Serial No.: 10/556,125

Art Unit: 3721

Filed: November 9, 2005

Conf. No: 4353

For: **ANASTOMOTIC STAPLE WITH CAPILLARY WHICH EXPELS A
BONDING AGENT UPON DEFORMATION**

Mail Stop: Appeal Brief - Patents
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APPEAL BRIEF

Sir:

This is an appeal from the Final Office Action dated June 17, 2010 and the Advisory Action dated August 25, 2010 for the above-identified patent application. This brief is accompanied by the requisite fee set forth in 37 C.F.R. § 1.17(f).

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being transmitted on the date below with the United States Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450, via electronic submission.

Dated: 11/3/2010



Lisa Anfuso

I. REAL PARTY IN INTEREST

The real party in interest for the above-identified application is Tyco Healthcare Group LP (d/b/a Covidien), having a principal office at 555 Long Wharf Drive, Suite 8 N1, New Haven, Connecticut 06511.

II. RELATED APPEALS AND INTERFERENCES

There are no other related prior or pending appeals or interferences for this application.

III. STATUS OF CLAIMS

The status of the claims in the above-identified application is as follows:

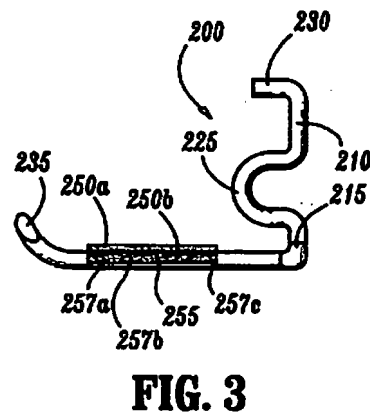
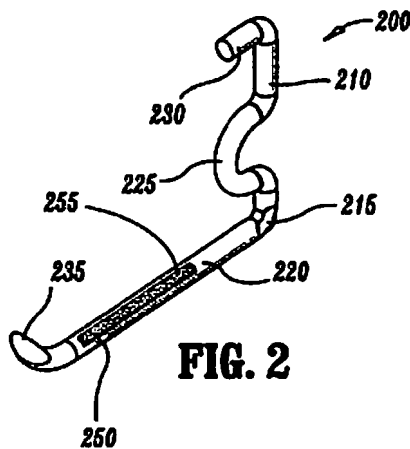
- A) Claims 1-8 are pending; and
- B) Claims 1-8 stand rejected and are under appeal.

IV. STATUS OF AMENDMENTS

An amendment was filed in this application on March 23, 2010 in response to the non-final Office Action mailed December 24, 2009. The amendment was entered by the Examiner. A Final Office Action was dated June 17, 2010 and an Advisory Action was dated August 25, 2010. No further amendments were filed in this application.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The anastomotic surgical fastener 200 recited in independent claims 1 and 2, which are hereby appealed, and which exemplary embodiments thereof are shown in Figs. 2, 3, 11, and 18a-c reproduced below, includes a base leg 220 and a support leg 210. See page 16, lines 1-2 and Figs. 2 and 3. Base leg 220 includes a distal end 235 which features a tip suitable for piercing tissue. See page 16, lines 3-5 and Figs. 2, 3, and 11. The base leg 220 is selectively deformable. See page 15, lines 4-14 and Fig. 11. Disposed along base leg 220 is a capillary 250 or 250a having one or more reservoirs 257a-257c. See page 16, line 19 through page 17, line 9; page 26, line 11-13; and Figs. 3 and 18a-c. The reservoirs retain a liquid. See page 17, lines 7-9. With respect to claim 1, the capillary 250 is rupturable simultaneously with the deformation of the surgical fastener to dispense the retained liquid upon being ruptured. See page 18, lines 7-9, and Fig. 11. With respect to claim 2, the capillary 250 is rupturable to dispense the liquid upon actuation of the surgical instrument simultaneously with the deformation of the surgical fastener. See page 18, lines 7-9; page 24, lines 16-18; and Fig. 11.



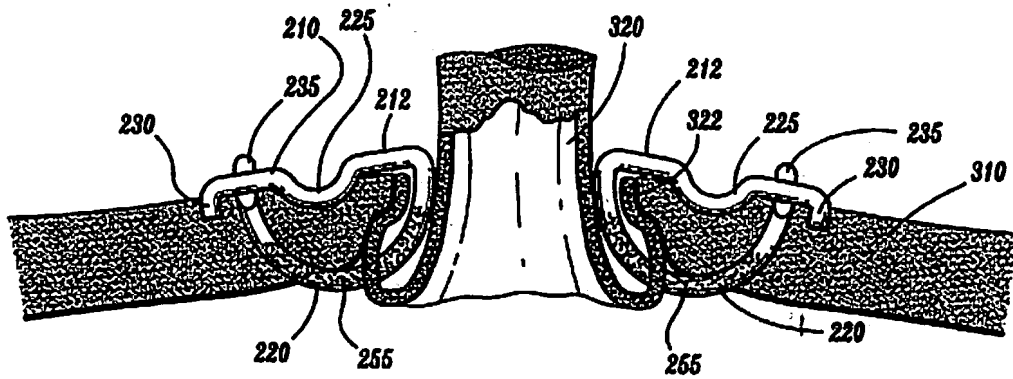


FIG. 11

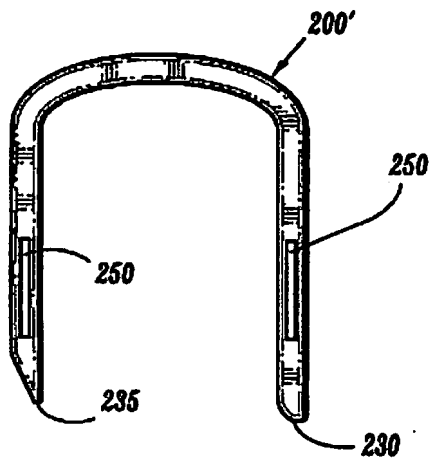


FIG. 18a

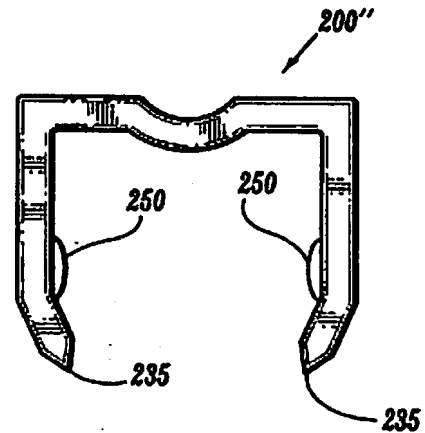


FIG. 18b

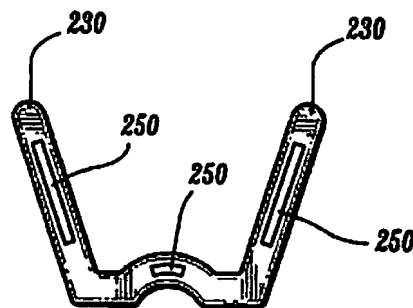


FIG. 18c

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant requests review of the following outstanding grounds of rejection:

A) The rejection of Claims 1-5, and 7 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,045,560 to McKean et al. (hereinafter “McKean”); and

B) The rejection of Claims 6 and 8 under 35 U.S.C. §103(a) as being unpatentable over McKean in view of U.S. Patent No. 5,263,629 to Trumbull et al. (hereinafter “Trumbull”).

VII. ARGUMENT

A) Claims 1-5, and 7 Stand Rejected Under 35 U.S.C. § 102(b) As Being Anticipated By McKean

Claims 1-5, and 7 stand rejected under 35 U.S.C. §102(b) as being anticipated by McKean. Regarding McKean, the Examiner remarked as follows:

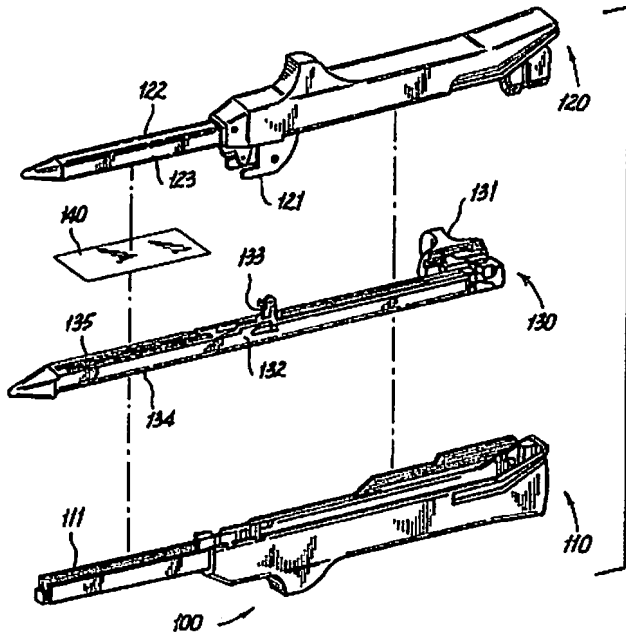
“In reference to claims 1-5 and 7, McKean et al. discloses a surgical fastener system comprising: a fastener including a base leg and a support leg, the base leg being selectively deformable and including at least one traumatic tip for piercing tissue, and at least one capillary 140 having a reservoir (cellulose material) therein for retaining a liquid (column 4 lines 13-30, line 67- column 5 line 4) such that the capillary is rupturable (penetrated by tip) with the deformation of the surgical fastener; a loading unit 135; and an actuator 132.”

Claim 1 recites a surgical fastener for use with an anastomosis of two tissues. The surgical fastener comprises a base leg and a support leg, said base leg being selectively deformable and including at least one traumatic tip for piercing tissue, and at least one capillary fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid, each of said at least one capillary being rupturable simultaneously with the deformation of said surgical fastener to dispense said liquid simultaneously upon being ruptured.

Claim 2 is directed to a surgical fastener for use with a surgical instrument for performing an anastomosis between two tissues wherein the surgical instrument includes a selectively engageable loading unit for supporting an array of surgical fasteners and an actuator for initiating deformation of the surgical fasteners, each of the surgical fasteners comprising a base leg and a support leg, said base leg being selectively deformable and including a tip for piercing tissue;

and at least one capillary fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid, each of said at least one capillary being rupturable to dispense said liquid upon actuation of the surgical instrument and simultaneously with the deformation of each surgical fastener.

McKean discloses a surgical stapling apparatus (100) (shown in Figs. 2 and 7 as reproduced below) having a first jaw structure (110) having a finger-like projection (111) for holding an actuating assembly a.k.a. a disposable loading unit (130). See McKean col. 3, lines 23-26. Disposable loading unit (130) is operatively associated with a cartridge assembly (135) that houses metal staples. See McKean col. 3, lines 31-32. The McKean apparatus includes a second jaw structure (120) having a finger-like projection for carrying an anvil assembly (123). See McKean col. 3, lines 26-29. Biocompatible surgical fabric (140) is disposed between the anvil assembly (123) and cartridge assembly (135). See McKean col. 3, lines 52-56. The Biocompatible surgical fabric (140) can be woven, knit, or nonwoven fabric. See McKean col. 4, lines 13-14. Biocompatible surgical fabric (140) is releasably attached the anvil assembly (123), the cartridge assembly (135), or both the anvil assembly (123) and cartridge assembly (135). See McKean col. 4, lines 31-36. Upon actuation of the McKean instrument, staples (137) penetrate the surgical fabric (140) and tissue (150) and a tissue/fabric “sandwich” is formed. See McKean col. 4, lines 37-38 and lines 57-59.



McKean Fig. 2

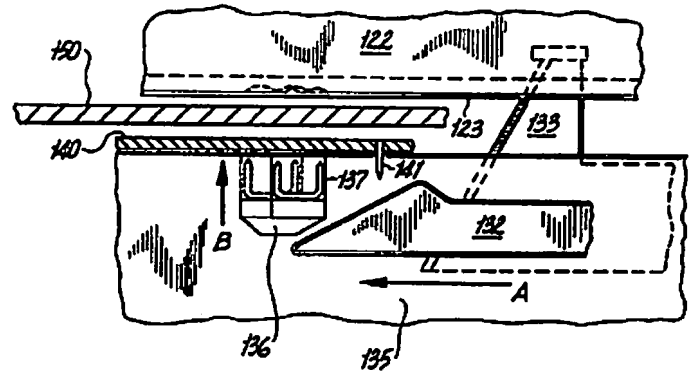


FIG. 7

McKean Fig. 7

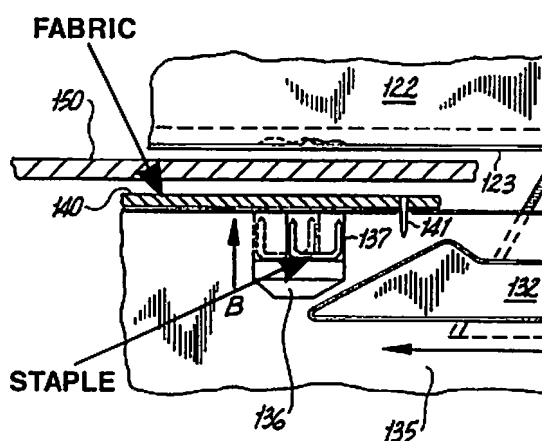
Under MPEP §2131, “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference.” See *Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Appellant respectfully submits that McKean fails to anticipate the anastomotic staple recited in Claims 1 and 2. More specifically, McKean fails to disclose the following elements recited in Claims 1 and 2:

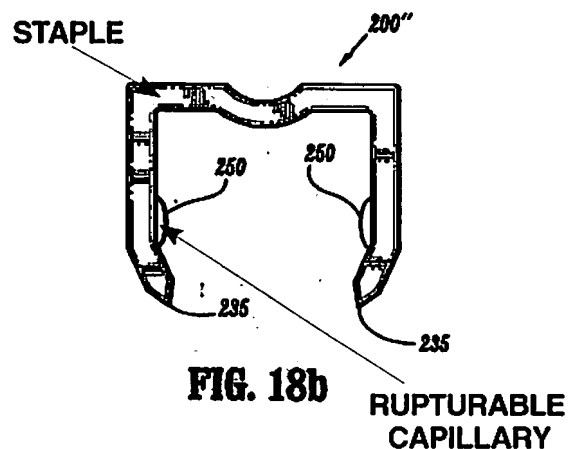
1. “at least one capillary fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid”
2. “each of said at least one capillary being rupturable simultaneously with the deformation of said surgical fastener to dispense said liquid simultaneously upon being ruptured”

As discussed above, McKean merely discloses the use of a surgical stapler with a surgical fabric buttress. The fabric placed between the staple and patient tissue so that, upon actuation of the stapler, the fabric is stapled to tissue. The Examiner asserts that the surgical fabric of McKean, *when stapled to a patient using the staple*, anticipates a “capillary fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid” as required by Appellant’s independent claims 1 and 2. Appellant contends that equating a fabric buttress to a rupturable capillary fixed to an external surface of at least one of the base leg or support leg grossly mischaracterizes Appellant’s invention.

Clearly, the McKean buttress is separate from the surgical staples, in contrast to the subject matter of claims 1 and 2 in which the capillary is part of the surgical fastener. McKean’s staples are housed in the cartridge assembly and deployed through the buttress and tissue. The distinction between the McKean reference and Appellant’s invention is clearly seen in the comparison between McKean Fig. 7 and Appellant’s Fig. 18b presented below. The McKean fabric 150 is separate and apart from the McKean staple 137, while Appellant’s rupturable capillary 250 is “fixed to an external surface of at least one of the base leg or support leg.”



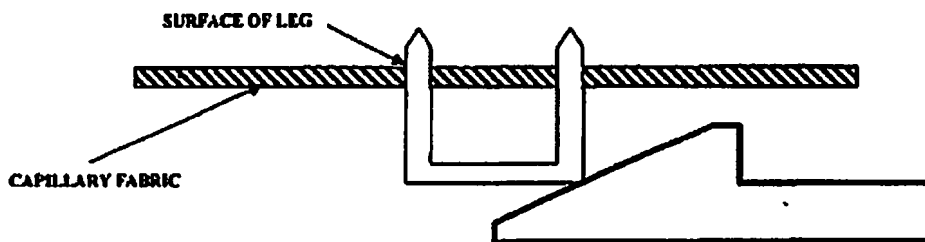
McKean Fig. 7



Appellant's Fig. 18b

Claims 1 and 2 require a “capillary fixed to an external surface of at least one of the base leg or support leg”. *Emphasis added.* On page 4, paragraph 6 of the Final Office Action, the Examiner takes the strained position that “as the fastener of McKean is pushed from the cartridge, the fastener will penetrate a fabric, which is porous (thereby defining a capillary structure), such that the fabric is fixed to an external surface of a leg of the fastener.” Appellant’s independent claims 1 and 2 further require “said at least one capillary being rupturable simultaneously with the deformation of said surgical fastener”. *Emphasis added.*

Furthermore, according to claims 1 and 2, the capillary is ruptured when the staple is deformed. There is no disclosure in Mc Kean that any part of the fabric buttress is ruptured. The examiner’s position that the buttress material somehow provides a capillary that is part of the fastener is unsupportable. As shown by the Examiner’s interpretive sketch, reproduced below, the staple penetrates the fabric at a point in time prior to the deformation of the staple, not “simultaneously with the deformation of said surgical fastener” as required by Appellant’s claims. An instantaneous event such as a rupture cannot occur both prior to and simultaneously with some other event. Therefore, the characterization of McKean devised by the Examiner cannot possibly meet the limitation recited in Appellant’s independent claims requiring “one capillary fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid, each of said at least one capillary being rupturable simultaneously with the deformation of said surgical fastener to dispense said liquid simultaneously upon being ruptured.”



Examiner's interpretation of the McKean device, Office Action mailed June 17, 2010, page 4.

Appellants submit that the Examiner's construction renders Appellant's invention unsuitable for its intended purpose. In particular, McKean's fabric is not suitable for Appellant's intended purpose, to wit, to "dispense said liquid simultaneously upon being ruptured." In the Final Office Action, the Examiner states:

Appellant has argued that McKean et al. fails to disclose a fastener having a "capillary fixed to an external surface of at least one of the base leg or support leg". As illustrated below, as the fastener of McKean is pushed from the cartridge, the fastener will penetrate a fabric, which is porous (thereby defining a capillary structure), such that the fabric is fixed to an external surface of a leg of the fastener.

The Examiner's scenario requires the capillary fabric to be ruptured in order for the capillary fabric to be fixed to an external surface of a leg of the fastener. However, as recited in Appellant's claims and as discussed in Appellant's specification, Appellant's claims require, *inter alia*, "the at least one capillary fixed to an external surface of at least one of the base leg or support leg...being rupturable simultaneously with the deformation of said surgical fastener to dispense said liquid simultaneously upon being ruptured." In other words, the Examiner's construction would require the capillary to be ruptured *before* the staple is deformed, which would negate the utility of Appellant's anastomotic staple and render it unsuitable for its intended purpose.

According to MPEP §2111, the pending claims must be “given their broadest reasonable interpretation consistent with the specification.” Applicant asserts that the examiner’s construction of the claims is not consistent with a “broadest reasonable” interpretation. However, even if the Examiner’s construction was reasonable, it would still require the capillary to be ruptured in order for it to be fixed to the fastener, which counter-intuitively requires the capillary be both “fixed” and “rupturable *simultaneously with the deformation.*”

According to MPEP §2131, each and every element as set forth in the claim must either expressly or inherently be described in a single prior art reference in order to show anticipation. The Examiner’s rationale in the Final Office Action fails this test. There is no express description of a capillary in McKean. There is no inherent description of a capillary in McKean. The mere fact a fabric may be porous, woven, non-woven, or knit does not inherently describe the presence of a capillary structure of the fastener. Nowhere does McKean teach a “capillary fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid.”

In the Advisory Action, the Examiner states that she “finds the structure of McKean to be capable of performing (*sic*) the claimed function, such that there is no claimed structural difference between the claimed invention and the disclosed structure of McKean; for example, the base of the surgical fastener is capable of being deformed as the points of the surgical fastener rupture the capillary element.” (See the Advisory Action mailed on August 25, 2010, continuation sheet, lines 3-7.) Appellant strongly disagrees. A person of ordinary skill would certainly not conclude the structure of McKean is capable of performing the function of Appellant’s invention as described and claimed. That is, one of ordinary skill in the art would

surely appreciate the differences between the McKean device and Appellant's invention, and would recognize the differences between at least the fasteners disclosed therein.

For all the reasons presented hereinabove, the Examiner's interpretation of Appellant's claims is neither reasonable nor consistent with the specification. MPEP §2111 further states that "the broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach." Appellant respectfully submits that that one skilled in the art after reading the present application would not interpret Appellant's claims in the manner purported by the Examiner.

For any one or all of the reasons discussed above, Appellant submits that Claims 1 and 2 are not anticipated by McKean and are in condition for allowance.

Claims 2-8 and 10 depend from claim 1. For at least the reasons discussed above, *inter alia*, Appellant submits that McKean fails to anticipate claims 3-5 and 7. Accordingly, Appellant submits that claims 3-5 and 7 are also in condition for allowance and that the rejection thereof under 35 U.S.C. §102(b) be withdrawn.

**B) Claims 6 and 8 Stand Rejected Under 35 U.S.C. § 103(a)
As Being Unpatentable Over McKean in view of Trumbull**

Claims 6 and 8 were rejected under 35 U.S.C. §103(a) as being unpatentable over McKean in view of U.S. Patent No. 5, 263,629 to Trumbull et al. (hereinafter Trumbull). Appellant respectfully traverses this rejection for at least the following reasons.

MPEP §2143.03 states that if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. Since Claims 6 and 8 depend from independent Claims 1 and 2 and contain all the limitations of Claims 1 and 2, for at least the

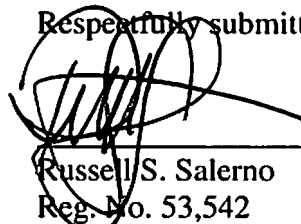
reasons presented above regarding the patentability of Claims 1 and 2, Appellant respectfully submits that since claims 1 and 2 as currently amended are patentable, claims 6 and 8 which depend therefrom are also patentable. Accordingly, Applicant respectfully requests the rejection of claims 6 and 8 be withdrawn.

In view of the foregoing remarks and arguments, Appellant respectfully submits that the rejection of Claims 1-5, and 7 under 35 U.S.C. §102(b) as being anticipated by McKean and the rejection of Claims 6 and 8 under 35 U.S.C. §103(a) as being unpatentable over McKean in view of Trumbull have been traversed. Accordingly, Appellant respectfully submits that Claims 1-8 are allowable over the references of record, and respectfully request allowance of these claims.

Please charge any deficiency, as well as any other fee(s) which may become due under 37 C.F.R. §1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s), to Deposit Account No. 50-2140. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required, and charge Deposit Account No. 50-2140 therefor.

Dated: November 3, 2010

Respectfully submitted,



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VIII. APPENDIX OF CLAIMS

1. (Rejected) A surgical fastener for use with an anastomosis of two tissues, comprising:

a base leg and a support leg, said base leg being selectively deformable and including at least one traumatic tip for piercing tissue; and

at least one capillary fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid, each of said at least one capillary being rupturable simultaneously with the deformation of said surgical fastener to dispense said liquid simultaneously upon being ruptured.

2. (Rejected) A surgical fastener for use with a surgical instrument for performing an anastomosis between two tissues wherein the surgical instrument includes a selectively engageable loading unit for supporting an array of surgical fasteners and an actuator for initiating deformation of the surgical fasteners, each of the surgical fasteners comprising:

a base leg and a support leg, said base leg being selectively deformable and including a tip for piercing tissue; and

at least one capillary fixed to an external surface of at least one of the base leg or support leg having a reservoir defined therein for retaining a liquid, each of said at least one capillary being rupturable to dispense said liquid upon actuation of the surgical instrument and simultaneously with the deformation of each surgical fastener.

3. (Rejected) A surgical fastener for use with an anastomosis according to any preceding claim wherein said liquid in said reservoir includes at least one of a bonding agent, medicinal agent and therapeutic agent.

4. (Rejected) A surgical fastener for use with an anastomosis according to any preceding claim wherein said reservoir includes a series of chambers, each of said chambers including a liquid disposed therein selected from the group consisting of: bonding agents, medicinal agents and therapeutic agents.

5. (Rejected) A surgical fastener for use with an anastomosis according to any preceding claim wherein said liquid is a bonding agent designed to adhere to tissue upon curing.

6. (Rejected) A surgical fastener for use with an anastomosis according to any preceding claim wherein said base leg of said surgical fastener includes first and second capillaries which are designed to sequentially rupture upon deformation.

7. (Rejected) A surgical fastener for use with an anastomosis according to any preceding claim wherein said first capillary includes a medicinal agent and said second capillary is designed to include a bonding agent.

8. (Rejected) A surgical fastener for use with an anastomosis according to any preceding claim wherein said surgical fastener includes at least two capillaries which are radially disposed along the base leg of said surgical fastener.

IX. EVIDENCE APPENDIX

None.

Application Serial. No.: 10/556,125
Notice of Appeal filed: September 9, 2010
Appeal Brief Dated: November 3, 2010

X. RELATED PROCEEDINGS APPENDIX

None.